In the United States Court of Federal Claims

No. 20-499C

(Filed under seal: November 21, 2022)
(Reissued: November 30, 2022)

GILEAD SCIENCES, INC., Plaintiff, **v.** **UNITED STATES,** Defendant.	Alleged breach of contract; post-trial decision on liability; deferral of one issue that will be before a district court in the trial of its closely related patent infringement case.

Ronald C. Machen, Jr., Wilmer Cutler Pickering Hale and Dorr LLP, Washington, D.C. for plaintiff Gilead Sciences, Inc. With him at the trial and on the briefs were David B. Bassett, Wilmer Cutler Pickering Hale and Dorr LLP, New York, NY, as well as Vinita Ferrera, Emily R. Whelan, George P. Varghese, Timothy A. Cook, and Stephanie Lin, Wilmer Cutler Pickering Hale and Dorr LLP, Boston, MA.

Walter W. Brown, Senior Litigation Counsel, Commercial Litigation Branch, Civil Division, United States Department of Justice, Washington, D.C. for the United States. With him on the briefs were Michael Granston, Deputy Assistant Attorney General, Gary L. Hausken, Director, and at the trial were Philip Charles Sternhell, Assistant Director, and Amanda K. Kelly, Carrie E. Rosato, Patrick C. Holvey, Matthew D. Tanner, Lucy Grace D. Noyola, and Lena Yueh, Trial Attorneys, Commercial Litigation Branch, Civil Division, United States Department of Justice, Washington, D.C.

OPINION AND ORDER[1]

LETTOW, Senior Judge.

This post-trial decision addresses the liability of defendant United States ("the government") for alleged breaches of contract. First Am. Compl. ¶ 1, ECF No. 33. Plaintiff Gilead Sciences, Inc. ("Gilead") alleges that the Centers for Disease Control and Prevention ("CDC") violated the terms of three Material Transfer Agreements ("MTAs") and two Clinical Trial Agreements ("CTAs"), under the terms of which Gilead provided its proprietary drugs free

[1] Because of the protective order entered in this case, this opinion was initially filed under seal. The parties were requested to review the decision and provide proposed redactions of any confidential or proprietary information. No redactions were requested.

of charge to the government for use in animal and human studies.[2] Specifically, Gilead argues that the government violated the MTAs by failing to notify Gilead of purported inventions the government investigators eventually patented. First Am. Compl. ¶ 125, 137, 144. Gilead contends that those inventions resulted from the research conducted under the MTAs, *see* First Am. Compl. ¶¶ 119-46, and that the government violated the CTAs by seeking patent protection on inventions Gilead argues derived from the studies covered by the CTAs, *see* First Am. Compl. ¶¶ 147-60.

In addition to the unusual nature of the substantive issues, this action is closely tied to a patent infringement case pending in the United States District Court for the District of Delaware styled *United States v. Gilead Scis., Inc.*, No. 19-2103 (D. Del., filed Nov. 6, 2019). There the government has accused Gilead of patent infringement for patents CDC obtained relating to a method of use for Gilead's developed drugs—the very patents Gilead contends were obtained as a result of breach of the agreements at issue here. Compl. ¶ 10, *Gilead Scis.*, No. 19-2103 (D. Del.). Discovery in that action and this one has been coordinated by the parties, but the case before that court is not scheduled for trial until May 2023. Hr'g Tr. 9:25 to 10:19 (Apr. 26, 2022).

The court held a seven-day trial in Washington, D.C., commencing on June 23, 2022 regarding the liability of the United States for allegedly violating the controverted contracts. Following post-trial briefing, *see* Pl.'s Post-Trial Br., ECF No.136; Def.'s Post-Trial Br., ECF No. 142; Pl.'s Post-Trial Reply, ECF No. 146, the court held closing arguments on October 26, 2022, in Washington, D.C. The issue of liability for alleged breaches of the MTAs and CTAs is ready for disposition.

FACTS[3]

A. Gilead's Development of Truvada for Treatment

Gilead is a biopharmaceutical company that has an extensive history of developing drug treatments to fight human immunodeficiency virus ("HIV"). First Am. Compl. ¶ 3; Tr. 70:20 to 71:15 (Alton).[4] The company's first success in treating HIV was the development of tenofovir disoproxil fumarate ("TDF"). Tr. 66:10 to 67:20 (Alton).[5] The FDA approved TDF for HIV

[2] The First Amended Complaint alleges the breach of four MTAs: MTA No. NCHSTP-V043072-00 ("the '072 MTA"), MTA No. NCHST-V053433 ("the '433 MTA"), MTA No. NCHSTP-V053471-00 ("the '471 MTA"), and MTA No. NCHSTP-V053649 ("the '649 MTA"). First Am. Compl. ¶ 45. On note, the '433 MTA was not addressed at trial or in post-trial briefing, and consequently the court does not consider it.

[3] This recitation of facts constitutes the court's principal findings of fact in accord with Rule 52(a) of the Rules of the Court of Federal Claims ("RCFC"). Other findings of fact and rulings on questions of mixed fact and law are set out in the analysis.

[4] Citations to the trial transcript are cited as "Tr. __ (Witness)." Citations to joint exhibits are shown as "JX__," plaintiff's exhibits are identified as "PX__," and defendant's exhibits are denoted as "DX___."

treatment in 2001, and Gilead markets the drug as Viread®. Am. Joint Stip. ¶ 3, ECF No. 115; Tr. 212:19-22 (Rooney).[6] While TDF was shown to be effective, HIV can quickly develop resistance to a single drug. Tr. 68:9-25 (Alton). In light of this reality, Gilead continued to research potential drugs to treat HIV in combination with TDF. Gilead's further drug that proved effective and safe for HIV treatment was emtricitabine ("FTC"). Tr. 67:21 to 68:8 (Alton); Tr. 213:15-23 (Rooney). Gilead markets FTC as Emtriva®, having received FDA approval for its use in 2003. Am. Joint Stip. ¶ 4.

Because of HIV's tendency to develop resistance to any given drug, patients were often required to take more than one drug at a time, which sometimes required multiple pills multiple times a day. Tr. 64:18 to 65:16 (Alton). Accordingly, Gilead sought to simplify the drug therapy. To do so, Gilead developed "a fixed-dose combination," that combined TDF and FTC. Tr. 69:6-14 (Alton); Am. Joint Stip. ¶ 5. That combination was and is called Truvada®, which received FDA approval for treatment in 2004 and allows HIV infected persons to take one pill for treatment as contrasted to several. Am. Joint Stip. ¶¶ 5-6.

Gilead invested a significant amount (more than a billion dollars) in developing TDF, FTC, and Truvada for treatment. Tr. 70:12-19 (Alton); Tr. 478:18-22 (Hitchcock). To protect its investment, Gilead sought and received several United States patents covering these drugs. As a result of its patents, Gilead held the exclusive right to sell Truvada until September 30, 2020. Pl.'s Post-Trial Br. at 6 (citing Compl. ¶ 190, *United States v. Gilead Scis., Inc.*, No. 19-2103 (D. Del. Nov. 6, 2019)).[7]

B. Gilead's Collaboration with CDC

Once TDF alone proved effective for treatment, researchers began to seek to collaborate with Gilead to study whether the drugs currently being used for treatment could also be used to prevent the contraction of HIV. *See*, *e.g.*, PX43; *see also* Tr. 534:12 to 535:7 (M. Miller). Researchers wished to explore the prevention of HIV via drug therapy in one of two modes with each mode centering on when the individual is exposed to the disease and when they take the drug in relation to that exposure. One mode, pre-exposure prophylaxis ("PrEP"), demands that the drug be administered, as the name indicates, prior to exposure to HIV. Tr. 215:20 to 216:11 (Rooney). The other mode, post-exposure prophylaxis ("PEP"), on the other hand requires that the drug be taken shortly after a potential exposure to the virus. Tr. 217:3-8 (Rooney).

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[5] TDF was the first drug Gilead developed to address HIV that reached the market. A prior drug, adefovir disoproxil fumarate, did not receive approval from the Food and Drug Administration ("FDA"). Tr. 66:12-20 (Alton).

[6] The use of a drug for treatment is for patients who have been infected with the disease. Using a drug for treatment is distinct from using a drug to prevent the contraction of the disease, known as pre- or post-exposure prophylaxis.

[7] In 2019 "Gilead announced a settlement that . . . permit[ted] marketing in the United States of a generic equivalent of the Truvada for PrEP® product from Teva Pharmaceuticals Industries Ltd. . . . , roughly one year ahead of the expiration of its Truvada-related patents," Compl. ¶ 190, *Gilead Scis.*, No. 19-2103 (D. Del.).

To address the various requests for collaboration from researchers, Gilead established a clinical operations team and application process to evaluate the requests for production of drugs for different research studies. Tr. 534:14 to 535:7 (M. Miller). Importantly, Gilead at that time did not sponsor or conduct its own PrEP clinical trials. Tr. 76:18 to 77:8 (Alton). Gilead represents that studying drugs for HIV PrEP was controversial at the time, and Gilead was hesitant to conduct clinical trials itself because "[t]here was concern about putting people onto clinical trials and the ethics of that, that it might expose them to more risk than [it was] actually helping." Tr. 75:20 to 76:17 (Alton). From a business standpoint, Gilead was concerned to avoid the appearance that it was encouraging disinhibition and unsafe sex practices. Tr. 104:11-21 (Alton).

Gilead and CDC began to collaborate to study TDF and a combination of TDF and FTC for PrEP purposes as early as 2004. Specifically, CDC sought materials for preclinical PrEP studies in monkeys. *See* First Am. Compl. ¶ 6; JX3 at 1. Gilead was willing to provide its product, and the parties entered negotiations to govern their collaboration. Tr. 585:11 to 599:24 (Enochs-Ochoa). Although the use of a Cooperative Research and Development Agreement ("CRADA") was discussed, both parties wished to proceed under an MTA. JX40 at 2-3; Tr. 592:12 to 593:3 (Enochs-Ochoa). The government sought to use its template MTA, but Gilead was concerned with protecting its intellectual property. *See* JX40 at 3-5; PX55 at 4; Tr. 591:7 to 594:16 (Enochs-Ochoa). Adela Enochs-Ochoa, a transactional attorney in Gilead's general counsel's office, was responsible for negotiating the language of an MTA with the government. PX55 at 4; Tr. 578:24 to 579:11, 580:11 to 581:21, 582:19 to 583:11, 584:8-17 (Enochs-Ochoa). Ms. Enochs-Ochoa negotiated with Lisa Blake-Dispigna, a technology transfer specialist with CDC, to reach language acceptable to both parties. *See* JX40 at 1-3; Tr. 589:16-21 (Enochs-Ochoa).

Ms. Enochs-Ochoa received a template of the government's standard MTA from Ms. Blake-DiSpigna, to which Ms. Enochs-Ochoa proposed changes to the template and submitted them to Ms. Blake-DiSpigna. JX40 at 3-4; Tr. 590:8-18 (Enochs-Ochoa). Ms. Blake-DiSpigna accepted "all of the proposed changes except term 8." JX40 at 3. Term eight of the template MTA was the intellectual property section of the agreement. Tr. 591:7-13 (Enochs-Ochoa). In particular, Ms. Blake-DiSpigna advised that the government could not "grant rights in advance under an MTA," which in turn caused Ms. Enochs-Ochoa to explain that Gilead's desire was to "have the right to be the first to negotiate an exclusive license to any IP developed by [government] researchers using [Gilead's] drug technology." JX40 at 3. After a back and forth of proposed language, the following text was incorporated into the MTAs:

> When Recipient is PHS: Recipient will promptly disclose to Provider all results, data, and other information or materials derived from Recipient's use of Research Material and Provider's Confidential Information ("Results") . . . . The ownership of any inventions, discoveries and ideas that are made, conceived or reduced to practice under this Agreement ("Inventions") either solely by Recipient's Investigator or jointly by Provider and Recipient's Investigator, and whether patentable or not, shall be determined in accordance with U.S. patent law on inventorship. *Recipient agrees to promptly notify Provider of any Inventions. The PHS shall retain title to any patent or other intellectual property rights in inventions made by its employees in the course of the Research Project.* The PHS is not authorized to promise rights in advance for inventions developed under this

> Agreement, however, *PHS agrees to give serious and reasonable consideration to Provider's request for a non-exclusive or exclusive license on commercially reasonable terms* under PHS's intellectual property rights in or to any Inventions.

JX3 at 3; JX5 at 3; JX6 at 3-4 (emphasis added).

Having reached an agreement on language, Gilead and CDC entered into the first MTA, the '072 MTA, on June 21, 2004. *See* JX3; Am. Joint Stip. ¶ 23; Tr. 485:19 to 486:7 (Hitchcock). The '072 MTA obligated Gilead to provide 55 grams of TDF in powder form and 2 grams of tenofovir in powder form to study the "prevention of simian human immunodeficiency virus (SHIV) infection in a low-dose rectal challenge model" in male macaques. JX3 at 1; *see* Am. Joint Stip. ¶¶ 24-25; Tr. 225:24 to 226:7 (Rooney); Tr. 624:5-22 (Subbarao). The '072 MTA was amended for the first time on January 24, 2005, calling upon Gilead to provide a further 200 grams of TDF in powder form to CDC "for the purpose of [o]ral [c]hemoprophylaxis with [TDF] to [e]valuate [v]aginal SIV [t]ransmission in a [r]hesus [m]acaque [r]epeat-[v]irus [e]xposure [m]odel." JX11 at 1; *see* Am. Joint Stip. ¶¶ 29, 32-33. The principal investigator for the study covered by the '072 MTA was Dr. Shambavi Subbarao. *See* JX3 at 5; Tr. 1311:12-15 (Heneine). Dr. Subbarao's studies showed that oral TDF was partially protective against simian HIV, a monkey form of HIV. *See* Tr. 1305:10-12 (Heneine); DX421 (publishing the results of the study).

The next MTA, the '471 MTA, was executed on January 31, 2005, following the same template as the '072 MTA. *See* JX5; Am. Joint Stip. ¶ 34; Tr. 1311:20 to 1312:21 (Heneine). "Pursuant to the '471 MTA, Gilead agreed to provide 250 grams of FTC [in powder form] for [a] macaque study directed to '[p]re-exposure prophylaxis with FTC in combination with one or two drugs for the prevention of simian human immunodeficiency virus (SHIV) infection in a repeat low-dose challenge model in'" macaques. Am. Joint Stip. ¶ 35 (quoting JX5 at 1); JX5 at 1; Tr. 1312:7-12 (Heneine). Dr. Walid Heneine was the lead investigator on this study. *See* JX5 at 5; Tr. 1312:1-3. Dr. Heneine's team of Drs. Gerardo Garcia-Lerma, Ron Otten, Tom Folks, and Rob Janssen implemented "multidrug regimens to see if that increase[d] the efficacy of PrEP in the model." Tr. 1305:15 to 1306:3 (Heneine). The initial project description included delivering tenofovir and FTC subcutaneously to female macaques. JX5 at 2. In January 2006, Dr. Heneine reached out to request an additional 300 grams of FTC under the '471 MTA and also proposed an amendment to the agreement to govern the additional request. *See* PX13 at 1; Tr. 1400:2 to 1402:20 (Heneine). Gilead provided the additional 300 grams of FTC without requiring an amendment to the '471 MTA. *See* Am. Joint Stip. ¶ 41; Tr. 495:15 to 496:14, 505:5-7 (Hitchcock). In February 2006, Dr. Heneine sought TDF for the '471 MTA to deliver to macaques orally with FTC "at dosing equivalent to that used in humans." *See* DX437. An amendment to the '471 MTA was entered on March 6, 2006, *see* JX12, and Gilead provided an additional 200 grams of TDF in powder form pursuant to that amendment, *see* Joint Am. Stip. ¶ 45; JX12; Tr. 498:5-8, 505:5-7 (Hitchcock).

CDC and Gilead entered the '649 MTA on April 25, 2005. JX6. This MTA obligated Gilead to provide 420 grams of tenofovir in powder form to be used in further monkey studies regarding PrEP. *Id.* at 1.[8] The monkey studies involved "evaluation of multidrug

[8] Under the '649 MTA, Gilead agreed to provide phosphonylmethoxypropyladenine or PMPA. PMPA is an acronym for tenofovir. JX6; Tr. 489:15-19 (Hitchcock).

chemoprophylaxis for the prevention of SHIV infection using the repeat-exposure macaque model." *Id*. at 1. Dr. Heneine was the lead investigator under this MTA as well. *Id*. at 5. Similar to its predecessors, this MTA was amended five times to provide additional amounts of the drugs and to extend the agreement. *See* JX13; JX14; JX15; JX16; and JX17; *see also* Am. Joint Stip. ¶¶ 55-79.

Based on the '471 MTA, *see* DX437, and the '649 MTA, *see* JX6, a study was conducted that involved four groups of monkeys. *See* DX425 at 1. The first group received injections of FTC alone in a human equivalent dose. *Id*. The second group received a combination of TDF and FTC orally in a dosage equivalent to the human dosage. *Id*. The third group received an injection of FTC in an equivalent dosage and tenofovir in doses higher than that given to humans in Truvada for treatment. *Id*. The fourth group received a regimen similar to group three but at different levels. *Id*. Only the monkeys in the third and fourth groups were fully protected from infection, while some monkeys in groups one and two became infected with SHIV. *Id*. Some results of the study were obtained before February 2006. *See* Tr. 1402:16 to 1403:16 (Heneine). The results were published in 2008. DX425.

C. CDC's Provisional Patent Application

Prior to February 3, 2006, Dr. Heneine filled out an Employee Invention Report that was provided to CDC's Technology Transfer Office. *See* PX615.[9] In the report, Dr. Heneine indicated that the materials used in the study were subject to MTAs, PX615 at 2, but he testified at trial that he did not remember whether he attached the MTAs as requested by the form; although, he indicated that the relevant persons had access to copies of the MTAs regardless of whether he complied with the form's instructions. Tr. 2002:3 to 2004:22 (Heneine: "That office has all the MTAs of CDC . . . . So whether I attach [the MTA] or I don't attach it is irrelevant."). Dr. Heneine also left blank the area of the Employee Invention Report asking for "any companies that may be good licensing prospects." PX615 at 2; *see also* Tr. 2005:15 to 2006:21 (Heneine). Dr. Heneine's contention is that the MTAs would have provided sufficient indication to the CDC that Gilead would want to license the purported invention, despite the fact that he did not provide the MTAs or identify Gilead. *See* Tr. 2006:3-14 (Heneine).

Dr. Sumita Ghosh, a patent advisor with the CDC Technology Transfer Office used the Employee Invention Report to determine whether Dr. Heneine and his team had an invention.

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[9] "Invention records are standard forms generally used . . . as a means for inventors to disclose to . . . patent attorneys that an invention has been made and to initiate patent action. They are usually short documents containing space for such information as names of inventors, description and scope of invention, closest prior art, first date of conception and disclosure to others, dates of publication, etc." *In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 802 n.2 (Fed. Cir. 2000).

The court notes that PX615 was the subject of a motion for *in camera* disclosure made during trial. *See* Pl.'s Mot. for *In Camera* Disclosure, ECF No. 124. The government claimed attorney-client privilege as to the document. Tr. 1197:8-17. Without waiving the government's privilege claim, the parties were able to reach an agreement to provide a redacted version of the document as PX615. The court then denied plaintiff's motion as moot. *See* Order of July 1, 2022.

Tr. 1404:11-16, Tr. 2241:15 to 2244:9 (Ghosh). Using the information in the report, Dr. Ghosh filed a provisional patent application on February 3, 2006. *See* PX447; Tr. 759:18-24 (Ghosh). Provisional Patent Application No. 60/764811 ("the provisional application") included 17 claims, indicating that the CDC thought it had an invention to disclose ("[y]ou don't draft 17 claims if you don't think that you had an invention disclosure"), Tr. 2345:24-25 (Blakeslee).

The 17 claims did not specify with particularity the material involved. Instead, they included a claim for "[a] composition for the prevention of HIV transmission comprising *a plurality of antiretroviral compounds*." PX447 at 24 (emphasis added). The claims also included one for "a method of preventing HIV infection in a subject, comprising administering to the subject a therapeutically effective amount of [the] composition . . . in sufficient amounts to prevent viral infection in a subject." *Id*. The claims contemplated the compound being provided by a variety of methods of delivery including "topical, oral and injectable." *Id*. at 25. Two claims included using "at least one" of a list of antiretroviral compounds in the plurality, including tenofovir and FTC. *Id*. at 24.[10] Truvada had not been studied for PrEP efficacy in humans at the time the provisional application was filed. Tr. 2214:20 to 2215:15 (Schenk).

Dr. Ghosh did not notify anyone at Gilead about the filing of the provisional application. Tr. 762:18 to 764:20 (Ghosh). Dr. Heneine also did not disclose to Gilead that he had filed a provisional application, Tr. 1407:2-10 (Heneine), despite admitting that he "relied on the results" of the '471 and '649 MTAs in the provisional patent application, Tr. 1403:8-11 (Heneine). Ms. Blake-DiSpigna, a technology transfer specialist and member of the Office of Administrative Services for CDC, Tr. 1625:20 to 1626:1 (Blake-DiSpigna), similarly did not disclose to Gilead that a provisional application had been filed, Tr. 1659:8-10 (Blake-DiSpigna). Ms. Suzanne Shope, a member of CDC's Technology Transfer Office, did not notify Gilead about the provisional application as she considered it was Ms. Blake-DiSpigna's and her office's job to monitor MTA obligations. Tr. 1170:5-25 (Shope).

D. The CTAs and Non-Provisional Patent Application

In August 2004 (similar to the timing of the '072 MTA), the parties entered into the first CTA. *See* JX1 at 1. This CTA ("the Extended Safety Study CTA") governed the provision of TDF ("the 'Study Drug'") and a placebo in a clinical trial entitled: "Phase II Extended Safety of Tenofovir Disoproxil Fumarate (TDF) among HIV-1 Negative Men who have Sex with Men." *Id* at 2. The purpose of the study was to determine the efficacy of TDF for long-term safety and

[10] Claim 4, which discussed the composition, and Claim 8, which discussed the method, stated, "wherein at least one of the plurality of antiretroviral compounds is selected from the group consisting of tenofovir, FTC, United States Food and Drug Administration approved drugs used in the treatment of HIV infection, generic drugs used in the treatment of HIV infection, United States Food and Drug Administration approved drugs used in the treatment of pediatric HIV infection and derivatives thereof." PX447 at 24.

The provisional application included experimental data in monkey studies combining tenofovir and FTC. PX447 at 15. The provisional patent claims did not explicitly combine tenofovir and FTC. *Id*. at 24-25.

PrEP against HIV-1. *See* Am. Joint Stip. ¶ 80-81.[11] The Extended Safety Study CTA was amended once for Gilead to provide additional drugs. *See* JX7. A second CTA ("the Botswana CTA"), was signed in November 2004, under which Gilead initially provided TDF and a placebo for a clinical trial entitled "Study of Safety and Efficacy of Daily Tenofovir Disoproxil Fumarate ('TDF') for the Prevention of HIV Infection in Heterosexually-Active Young Adults in Botswana." JX2 at 2.[12] The Botswana CTA was amended three times. It was first amended to switch the study drug from TDF alone to a combination of TDF and FTC in September 2006 (what Gilead markets as Truvada), *see* JX8 at 1, and started enrolling participants in 2007. Tr. 882:21 to 883:2 (Celum). The Study Drug was changed from TDF to Truvada after the monkey "data from the combination of tenofovir-FTC show[ed] a high protection." Tr. 1374:19 to 1375:25 (Heneine); DX 1090 at 15; *see also* Tr. 694:20-25 (Paxton). The Botswana CTA was amended twice more to provide for more drugs. JX9, JX10. Gilead supplied the drugs it was contractually bound to provide under both CTAs and their respective amendments. Tr. 562:13 to 564:15 (M. Miller); Tr. 715:19 to 716:8 (Paxton).

Like the MTAs, the parties engaged in a negotiation of language that would govern any intellectual property that resulted from the trials and the CTAs. Gilead initially proposed that it would "solely own any and all inventions, made, conceived, or reduced to practice during the course of the study that are directly related to the study drug." JX34 at 3. CDC represented that it could not grant such rights under a CTA and countered with language that it would "promise not to patent any invention that result[ed] from use of the partner[']s material but instead to publish the results, thus assuring unfettered access by the partner to any CDC subject invention." JX34 at 3. The parties ultimately agreed on the following text for the two CTAs' Intellectual Property clauses:

> Ownership of inventions from the Trial shall be determined in accordance with inventorship under U.S. patent law. The Study Drug and any related confidential information disclosed to CDC by Gilead will remain Gilead's property. *CDC agrees to put the results of the Trial, patentable or otherwise, in the public domain* for all to use without obligation or compensation to CDC. For clarity, *CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial*.

JX1 at 3 (emphasis added); JX2 at 3. Having entered into the two CTAs, the trials proceeded with Gilead providing its drugs pursuant to the CTAs. The Extended Safety Study concluded that oral TDF was safe for long-term use in uninfected men. PX228 at 1; Tr. 875:11-18 (Celum); Tr. 692:15 to 693:19 (Paxton). In turn, the Botswana Study concluded that "[d]aily [oral] TDF-FTC prophylaxis prevented HIV infection in sexually active heterosexual adults." DX1090 at 14.

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[11] The principal investigator of the study was Marta Ackers. *See* Tr. 544:10-21 (M. Miller). Dr. Robert Grant was a co-investigator. Tr. 878:9-22 (Celum).

[12] The principal investigators were Dr. Dawn Smith, Tr. 732:3 to 736:1 (Smith) and Dr. Lynn Paxton, Tr. 552:22 to 553:7 (M. Miller). Dr. John Brooks also served as a short-term primary investigator on the Botswana trial. Tr. 716:23 to 718:5 (Paxton).

CDC filed a non-provisional patent application on January 31, 2007. *See* JX23. This application claimed priority to the provisional application. *Id*. at 6. Dr. Subbarao, the lead investigator of the study conducted under the '072 MTA, was neither consulted about the non-provisional application nor included as an inventor, *Id*. at 3-5; Tr. 625:7-25 (Subbarao), although her study was cited, JX23 at 27, while Dr. Heneine was cited, consulted, and included as an inventor, Tr. 1425:13 to 1426:8 (Heneine); *see* JX23 at 3, 27. The non-provisional patent application included combining FTC and "tenofovir or a tenofovir ester,"[13] but the claim was not included in the final issued patent. JX23 at 799.

In addition to the two CTA studies, two additional trials were conducted outside of CTA agreements, but using drugs donated by Gilead. In 2007, the Preexposure Prophylaxis Initiative ("iPrEx") study was sponsored by NIH to study whether a combination of TDF and FTC delivered orally was safe and effective in men who have sex with men and transgender women. DX1292 at 1. "Study drugs were donated by Gilead Sciences." *Id*. at 12.[14] The study participants were in "Peru, Ecuador, South Africa, Brazil, Thailand, and the United States." *See Id*. at 2. An additional study, which enrolled participants in 2008, the Partners PrEP study, concluded that "[o]ral TDF and TDF-FTC both protect against HIV-1 infection in heterosexual men and women." PX226 at 1-2. "Gilead Sciences donated the study medication but had no role in the data collection, data analysis, or manuscript preparation." *Id*. at 2.

E. FDA's Approval of Gilead's Truvada for PrEP

In 2009, with various clinical trials underway, the FDA, via Dr. Debra Birnkrant (director of the FDA Division of Antiviral Products), encouraged Gilead to seek an indication—or approval from the FDA—that Truvada may be used for PrEP. Tr. 447:5 to 449:2, 451:16-21 (Birnkrant); *see* DX75 at 3 ("The [Division of Antiviral Products] strongly recommended that Gilead work . . . to prepare the data in a reviewable format that could be submitted for the PrEP indication."). The CDC also advocated that Gilead seek an indication for Truvada to be used for PrEP. Tr. 709:1 to 710:1 (Paxton). Despite its concern about a PrEP indication encouraging disinhibition, Gilead was persuaded to seek FDA approval to use and market Truvada for PrEP. Tr. 104:11-21, 105:15 to 106:14 (Alton). The CDC did not disclose at that time to either Gilead or FDA that it had filed a patent application for HIV PrEP compounds. Tr. 457:6-18, 462:9-20 (Birnkrant). Dr. Heneine attended meetings with Gilead in which the company was being urged to seek an indication for PrEP related to Truvada, PX188 at 3; Tr. 307:11-13 (Rooney), Tr. 709:24 to 712:3 (Paxton), and he did not disclose at that time that he had pending patent applications. *See* Tr. 1476:3 to 1478:19 (Heneine).

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[13] "The process of claim 1 wherein said nucleoside reverse transcriptase inhibitor is emtricitabine and said nucleotide reverse transcriptase inhibitor comprises tenofovir or a tenofovir ester." JX23 at 263.

[14] "Gilead Sciences donated both FTC-TDF and placebo tablets and provided travel-related support for meetings conducted by non-Gilead investigators. The role of Gilead Sciences in the development of the protocol was limited to sections regarding the handling of the study drugs. Neither Gilead Sciences nor any of its employees had a role in the accrual or analysis of the data or in the preparation of the manuscript. DAIDS agreed to give Gilead 30 days to comment on the manuscript, but there was no agreement to accept suggestions." DX1292 at 3.

Gilead, per FDA's request, provided information about the results of the Extended Safety Study and the Botswana Study as they related to Truvada for PrEP. PX216; Tr. 713:20 to 714:14 (Paxton). FDA approved Truvada for PrEP in 2012, extending Truvada's approved use beyond treatment (to which Gilead's prior approval in 2004 solely related). Am. Joint Stip. ¶ 7; *see supra*, at 3. In its approval memo, FDA partially relied on the clinical trials covered by the CTAs in granting its approval for the PrEP indication. *See* JX38 at 4-6.[15]

F. The Inventors' Disclosures (or Lack Thereof)

During the course of events, Dr. Heneine and his co-inventors did not disclose their patent applications to several pertinent individuals. Dr. Subbarao, who conducted the monkey study under the '072 MTA, testified she was not aware of the patent applications until April 2019. Tr. 621:4 to 622:24 (Subbarao). The Director of CDC's National Center for HIV, AIDS, Viral Hepatitis, STD, and TB Prevention, Rear Admiral Jonathan Mermin, did not become aware of the patent application until 2016. *See* PX240; Tr. 745:13 to 746:19 (Mermin). Dr. Lynn Paxton, the CDC section head of the division of HIV AIDS who oversaw the PrEP clinical trials, Tr. 669: 22 to 670:11, 670:24 to 671:19 (Paxton), did not learn about the patent applications until 2018, Tr. 723:6 to 724:12 (Paxton). Despite the fact that Dr. Paxton and Dr. Heneine traveled to Botswana together to seek approval for the Botwsana CTA PrEP trial, Dr. Paxton did not recall Dr. Heneine telling her that he had a patent application pending related to the outcome of the study. Tr. 719:22 to 720:21 (Paxton). Similarly, Dr. Dawn Smith, a principal investigator of the Botswana study and a CDC employee, did not learn of the patents until they had already issued. *See* Tr. 732:16-20 (Smith). Dr. Smith worked with Dr. Heneine on the writing committee for CDC's 2014 PrEP guidelines; these guidelines instructed the public to use Truvada for PrEP purposes. *See* DX447; Tr. 739:6 to 740:4 (Smith). Dr. Smith did not know about Dr. Heneine's pending patent applications in 2014 when writing the guidelines; she stated that she considered Dr. Heneine's involvement in drafting the guidelines while he had a patent application pending—and therefore a financial interest in recommending Truvuada for PrEP—to be a conflict of interest. Tr. 739:21 to 740:4 (Smith). Dr. Heneine was removed from the writing committee once the Dr. Smith became aware of the then-issued patent. Tr. 735:3-6 (Smith).

The FDA was also not told of the pending patent applications. Dr. Heneine participated in calls with FDA regarding approving Truvada for PrEP but did not disclose the patent applications, despite having a potential financial interest in Truvada being approved for PrEP.

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[15] In its memo, FDA stated, "CDC's Phase 2 trial 4323 [Extended Safety Study] was reviewed in support of safety." JX38 at 4. It also stated,

> Top-line summaries from CDC's TDF2 trial . . . were also reviewed. TDF2 was conducted in Botswana, a country with an HIV prevalence of 17.6% (2008), in heterosexual males and females considered to be at high risk. TDF2 was a phase 3 trial that compared Truvada to placebo . . . . TDF2 was not powered to show a statistically significant effect on risk reduction by gender. *Even though the trial closed early for futility* as it was determined that more participants needed to enroll to maintain the power to identify a treatment effect, the overall results showed a risk reduction of 62% (95% CI22-83).

JX38 at 5-6 (emphasis added).

See Tr. 719:8-720:21 (Paxton); Tr. 745:13 to 746:19 (Mermin). Dr. Mermin testified that in his estimation "if one of the inventors were presenting to the FDA related to a regulatory decision, then it's important for those inventors and it's beneficial to those inventors to disclose any potential financial interest that they would have." Tr. 743:9-17 (Mermin).

Neither Dr. Heneine nor his co-inventors (nor anyone else in the government) timely informed Gilead about the pending patent applications. Tr. 249:11-19, 252:13-18, 254:23 to 255:1, 259:10-14, 259:20-24, 263:14-17, 264:11-15, 271:4-7, 272:19 to 273:1, 294:8 to 295:9 (Rooney); Tr. 1403:17 to 1404:10, 1418:18-24, 1443:11 to 1446:23 (Heneine) (admitting he did not notify Gilead of the patent applications at the time of filing, and that notifying materials providers "is not something I do"); Tr. 660:10 to 663:2 (Garcia-Lerma) (admitting he "never disclosed [the] patent application" to Gilead). The patent applications were not disclosed at a 2007 meeting of the HIV Prevention Trials Network that Dr. Heneine attended and at which co-inventor Dr. Folks gave a presentation regarding the monkey studies conducted under the MTAs that led to the filing of the provisional patent application. This meeting occurred a year after the filing of the provisional application and was only three weeks prior to the filing of the non-provisional patent application. *See* PX124; Tr. 1418:25 to 1422:4 (Heneine). Dr. Heneine did not include the patent applications in a presentation on the monkey studies at the 2008 Conference on Retroviruses and Opportunistic Infections ("CROI") or at the meeting with Gilead he had while at that conference. *See* Tr. 1428:17 to 1429:18 (Heneine) ("Q. And you didn't think to mention anything about your PrEP patent applications to Gilead at this meeting, right? A. Correct."); *see also* DX241. In an email sent in 2016, Dr. Heneine told Dr. Mermin that Gilead had "not been approached yet" about licensing the PrEP patent and acknowledged that "Gilead may decide to fight or litigate." DX444 at 1. Dr. Heneine's co-inventors similarly did not take it upon themselves to tell Gilead about the pending patent applications. *See* Tr. 617:24 to 618:10 (Otten); Tr. 612:6 to 613:8 (Folks); Tr. 1257:8-14, 1263:5-13 (Janssen).[16]

The CDC likewise did not timely alert Gilead to the patent applications. The lack of communication between CDC and Gilead in part may have occurred because there was internal disagreement on whose responsibility it was to satisfy contractual obligations associated with studies and trials. For example, Lisa Blake-DiSpigna (a CDC technology specialist working in the Office of Administrative Services) did not notify Gilead—despite being aware of the MTAs and the patent applications, Tr. 1659:8-10 (Blake-DiSpigna), because she believed it was the responsibility of the CDC Technology Transfer Office to do so, Tr. 1641:2-11 (Blake-DiSpigna). On the other hand, Dr. Ghosh and Ms. Shope—both employees of the CDC technology transfer office—did not disclose the applications to Gilead and both believed it was the responsibility of

[16] Dr. Garcia-Lerma applied for a job at Gilead in 2012 but did not disclose the patent application and even removed references of it from his CV. Tr. 650:6 to 651:24, 654:5 to 655:24 (Garcia-Lerma). Similarly, Dr. Janssen did not recall telling anyone at Gilead about the patents, despite working there for two years. Tr. 1257:8-14; 1263:5-13 (Janssen). In 2008, Dr. Janssen completed Gilead's Employee Confidential Information and Inventions Agreement when he applied for a job and was hired at Gilead. Dr. Janssen listed the international patent application number rather than the US patent application number, DX128 at Ex. A, as instructed by Dr. Heneine, Tr. 1242:24 to 1243:8 (Janssen), *see* DX552. Dr. Heneine sent his CV, which included the provisional patent application number, to Gilead when exploring jobs there in 2008 and 2010. *See* DX854 at 4; Tr. 1284:6 to 1285:21 (Janssen).

the Office of Administrative Services to do so. *See* Tr. 762: 2-17, 763:2-5 (Ghosh); Tr. 1170:11-20 (Shope).[17] This disagreement may reflect the fact that "CDC does not have a policy to track . . . those commitments, CDC programs." Tr. 778:4-10 (Cyril). Dr. Juliana Cyril, the government's designee on MTA policies and procedures at CDC, testified that the responsibility to notify Gilead fell to the individual investigators, which in this case centered on Dr. Heneine. Tr. 779:25 to 780:21 (Cyril).

The disclosures the government claimed at trial to satisfy the notice required under MTAs were generic annotations to articles published regarding the results of the trials along with general presentations, brochures, and public or standardized notifications. In addition to the previously discussed presentations at the 2007 HIV Prevention Trial Network and the 2008 Presentation at the CROI Conference, as well as employment forms and CVs, the government claimed that 12 articles satisfied the government's notification obligation. Def.'s Post-Trial Br. at 28-36. The government argued that an article published in *PLoS Medicine* in 2008, "Prevention of Rectal SHIV Transmission in Macaques by Daily or Intermittent Prophylaxis with Emtricitabine and Tenofovir" emailed by the CDC to Gilead on February 1, 2008, satisfied its notification obligation.[18] The competing-interest section of the article mentions a patent application stating, "Competing Interests: Authors JGGL, RAO, RJ, TMF, and WH are named in a US Government patent application related to methods for HIV prophylaxis." DX425 at 1. The competing-interest section does not identify the patent application numbers, the title of the patent applications, the products or compounds involved in the patent applications, or the MTAs. Tr. 1431:23 to 1433:7 (Heneine). The references in a competing-interest section do not necessarily "directly relate[] to the content of the manuscript," *see* Tr. 366:18 to 367:5, 385:2-7 (Rooney), and prophylaxis can relate to "multiple different things," Tr. 433:4-7 (Rooney). The body of the article states that the research published in the article used TDF, FTC, and tenofovir and that Gilead provided the drugs through an MTA, but it does not mention the patent applications. *See* DX425 at 2.[19] The other eleven articles, which were published between 2010 and 2016 after the *PLoS Medicine* article, contain similar competing-interest or conflicts-of-interest sections. *See* Tr. 359:17 to 398:4 (Rooney).[20] Only three articles, one published in 2014

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[17] The Office of Administrative Services and the CDC Technology Transfer Office merged into a single office in 2013, well after the filing of the provisional application. Tr. 1627:14-19 (Kirby).

[18] Dr. Heneine emailed Gilead the final version a week before its publication, after it was already accepted by *PLoS Medicine*. He did not ask for comments from Gilead. Tr. 1430:19-25 (Heneine); DX443.

[19] Dr. Heneine also emailed a draft of the published article to Dr. Rooney in March 2007. Tr. 1422:22 to 1424:11 (Heneine); DX441. The draft article was emailed about a month after the non-provisional patent application was filed. Tr. 1424:23 to 1425:11 (Heneine). The draft did not contain a competing-interest section. *See* Tr. 277:25 to 279:12.

[20] DX1258 (published 2010); DX1259 (published 2012); DX1260 (published 2012); DX1261 (published 2013); DX1262 (published 2014); DX1263 (published 2014); DX1264 (published 2015); DX1265 (published 2016); DX1266 (published 2016); DX1267 (published 2016;); DX1268 (published 2016).

and two in 2016, listed either an application or a patent number in the competing-interest section. DX1262; DX1267; DX1268.[21]

The government also claimed that public and standardized notifications, including its brochures, a *Federal Register* notice, an email from NIH's Licensing and Patenting Manager, and a Derwent Patent Index Report satisfied its notification obligation. The CDC Technology Transfer Office brochures list technology covered by HHS Patents for license. Gilead was not sent these brochures. *See* Tr. 767:25 to 768:3 (Ghosh). The brochures were created after the provisional patent application and first listed, "Prevention of Rectal SHIV Transmission," in 2006, DX329 at 34, Tr. 1188:5 to 1189:24 (Shope), and then "Prevention of Rectal HIV Transmission," in 2008, DX901 at 43. In August 2008, a Derwent Patent Index was emailed internally at Gilead, which described the non-provisional U.S. and the international patent applications. DX637 at 1209478. In 2009 a brochure was linked to the '547 patent application on the PTO website. DX902 at 44. The 2014 list of pending patent applications in a NIH *Federal Register* notice happened eight years after the filing of the provisional patent. DX572. The CDC published this notice "to advertise [its] technologies broadly." Tr. 1700:4-9 (Kirby). In addition, a 2014 email from an NIH Licensing and Patenting Manager to Gilead, asking if the company was interested in partnering with the CDC with Truvada for PrEP and stating that the CDC was pursuing a patent, was a standardized email sent to other companies. DX43. The government also claimed that it notified Gilead in 2016 when it emailed the company about the patents the government was issued, stating that Truvada "may be covered." DX577 at 2514706.

G. The Issued Patents

Despite the provisional patent application having been filed in 2006 and the non-provisional patent application having been filed in 2007, the patents did not issue until years later. The claims of the patent application were rejected at least four times prior to 2014. Tr. 804:8-11 (Siegel). In 2014, CDC significantly amended the non-provisional patent application, withdrawing all of the pending claims and submitting entirely new claims covering the TDF and FTC combination for PrEP in humans. JX23 at 563-68, 799-800; Tr. 810:23 to 812:1 (Siegel). While the provisional patent application claims covered "[a] composition for the prevention of HIV transmission comprising *a plurality of antiretroviral compounds*," PX447 at 24 (emphasis added), "[a] method of prevent[ion]," *id*. at 24, and "topical, oral and injectable" delivery, *id*. at 25, the 2014 application claims included combining FTC and tenofovir or TDF and delivering it orally to prevent infection in a primate host, JX23 at 785-86. The claims included the dosage of FTC and TDF. JX23 at 566. The patent examiner amended the two independent claims in the 2014 application to include that the "combination is administered orally." JX23 at 786. When explaining why the patent application was granted, the patent examiner stated, "[a]s amended, the claims are drawn to the employment of [a] particular combination of tenofovir and emitricitabine for protecting a primate, particularly a human from immunodeciency retrovirus, particularly HIV, or for inhibiting (hinder; restrain) the establishment of HIV self-replicating in a human, wherein the subject has not been infected with the virus." *Id*. Also, while the provisional patent application did not cite to any human clinical trials, the 2014 application included the published results from one human clinical trial regarding PrEP, the iPrEx human

[21] The article published in 2014 listed a patent application number and title. DX1262 at 9. One article published in 2016 listed a patent number and stated the patent was granted on June 2, 2015, DX1267 at 129, and the other article published in 2016 listed a patent number, DX1268.

trial (the Grant study) sponsored by NIH. Tr. JX23 at 569-78, 769; Tr. 812:2 to 813:8 (Siegel); DX1292 at 2.[22] The first patent, U.S. Patent No. 9,044,509 ("the '509 Patent"), then issued on June 2, 2015. *See* DX418. Every claim in the '509 patent was a claim that was added in the 2014 amendment to the non-provisional '547patent application. Tr. 819:1-4 (Siegel). Three additional patents have issued, and four patent applications remaining pending before the patent office. *See* JX20; JX21; JX23; Tr. 819:18-23, 822:22 to 823:6 (Siegel). The government continues to prosecute the pending applications. Tr. 822:22 to 823:6 (Siegel).

H. Damages

Gilead gave the Government free drugs as part of its MTAs and CTAs. *See* JX1, JX2, JX3, JX5, JX6. Its damage claims do not emphasize that circumstance but rather focus on the government's lack of timely notice of the patent application and the resulting lost opportunity to challenge and comment on the application and, alternatively, timely to license any resulting patents. *See* Pl.'s Post-Trial Br. at 56-60. It also cites the costs for the Delaware patent infringement litigation. *Id*. at 52. The government focuses on the cost of the drugs supplied by Gilead under the MTAs and CTAs. *See* Def.'s Post-Trial Br. at 58-72.

PROCEDURAL HISTORY

The government contacted Gilead in 2016, almost a year after the first patent ('509) issued in June 2015. DX577 at 1; JX 23. Specifically, Dr. Tara Kirby of the National Institutes of Health ("NIH") emailed Gilead on March 11, 2016, stating that the government had "recently obtained issued patents for this invention in a number of jurisdictions, including the United States (USPN 9,044,509), and [the government] believe[d] that . . . Truvada[] may be covered by these patents." DX577 at 1. After investigation and negotiation, Gilead filed *inter partes* review petitions to challenge the patents' validity. PX264; Tr. 790:9 to 791:1 (N. Miller). Those petitions were denied. Tr. 2084:8-14 (Schenk).

On November 6, 2019, the government sued Gilead in the District of Delaware, alleging that Gilead infringed its patents by selling and promoting Truvada and a related drug, Descovy, for HIV PrEP, First Am. Compl. ¶ 115, and seeking more than a billion dollars in damages, Tr. 1395:15-19 (Heneine). In turn, Gilead filed suit in this court in 2020, alleging that the government breached the MTAs and CTAs. *See generally* First Am. Compl.; Compl., ECF No. 1. The court entered a protective order in this case on June 28, 2021, ECF No. 43, which was subsequently amended on September 2, 2021, ECF No. 50. The court has held that it possesses jurisdiction over the action and declined to dismiss the case. *See Gilead Scis., Inc. v. United States*, 151 Fed. Cl. 742 (2020); *Gilead Scis., Inc. v. United States*, 155 Fed. Cl. 336 (2021). The court bifurcated the issues of liability and damages, while acknowledging that "some indication of damages" would be required during the liability phase of the case. Hr'g Tr. 26:2-13; 36:23-24 (Apr. 6, 2021), ECF No. 26.

[22] In part citing the Grant Study, the patent examiner stated "Importantly, the application shows that the combination has superior effect as compared to tenofovir alone in animal model and evidence[] on the record has shown the claimed combination has clinically significant results, which would not have been expected in view [of] the prior art as a whole." JX23 at 787.

After the parties completed discovery for the liability phase, the court held a seven-day trial beginning on June 23, 2022. Before trial began, Gilead filed three motions *in limine* and the government filed one. The court denied those motions. *See Gilead Scis., Inc. v. United States*, 160 Fed. Cl. 330 (2022). Following post-trial briefing and closing argument, the case is ready for disposition on the issue of liability.

STANDARDS FOR DECISION

To recover for breach of contract, Gilead must establish four elements: "(1) a valid contract between the parties, (2) an obligation or duty arising out of the contract, (3) a breach of that duty, and (4) damages caused by the breach." *San Carlos Irrigation & Drainage Dist. v. United States*, 877 F.2d 957, 959 (Fed. Cir. 1989). Gilead bears the burden of proving each element by a preponderance of the evidence. *See Fields v. United States*, 147 Fed. Cl. 352, 355 (2020). For the first element, the government has stipulated that there were five valid agreements. Am. Joint Stip. ¶¶ 23031, 34-44, 49-78, 80-88, 91-108. As to the last element, Gilead must show that "(1) the damages were reasonably foreseeable by the breaching party at the time of contracting; (2) the breach [was] a substantial causal factor in the damages; and (3) the damages are shown with reasonable certainty." *Indiana Michigan Power Co. v. United States*, 422 F.3d 1369, 1373 (Fed. Cir. 2005).

ANALYSIS

A. Affirmative Defenses

1. Statute of limitations.

Under 28 U.S.C. § 2501, monetary claims in this court are subject to a six-year statute of limitations. A claim accrues under 28 U.S.C. § 2501 "when all events have occurred to fix the [g]overnment's alleged liability, entitling the claimant to demand payment and sue here for his money." *Nager Elec. Co. v. United States*, 177 Ct. Cl. 234, 240 (1966) (footnote omitted). The accrual-suspension doctrine applies when the plaintiff shows "that defendant has concealed its acts with the result that plaintiff was unaware of their existence or . . . that its injury was 'inherently unknowable' at the accrual date." *Martinez v. United States*, 333 F.3d 1295, 1319 (Fed.Cir.2003) (*en banc*) (quoting *Welcker v. United States*, 752 F.2d 1577, 1580 (Fed. Cir. 1985)).

The government contends that the six-year statute of limitations bars Gilead's claims. Def.'s Post-Trial Br. at 34. It argues that Gilead had a right to bring a breach of contract suit when the government sought patent protection by filing the provisional patent application in 2006. *See Id.* at 37-39. It also asserts that damages, the fourth element of the claim, were caused at the time of the breach, in 2006. *Id.* at 39. The government argues that the damages were "the cost and value of the drugs" provided by Gilead, and that these were "ascertain[able] at that time." *Id.* The government concludes that Gilead's 2020 complaint is therefore barred. *Id.* The government then avers that the accrual-suspension doctrine does not apply because "[t]he [a]lleged [b]reaches [w]ere [n]ot [concealed] or [inherently unknowable] to Gilead." *Id.* The government relies on evidence of prompt notification to show that the claims were not concealed and not inherently unknowable. *See id.* at 39-42. The government also invokes substantial compliance and waiver as affirmative defenses. *Id.* at 54-58.

Gilead counters that the six-year statute of limitations does not bar its claim. Pl.'s Post-Trial Reply Br. at 11. It argues that the six-year clock did not start until the patent was issued in 2015, at which point Gilead suffered damages because the government gained an enforceable patent right. *Id.* at 11-12. It reasons that before this time, it was not evident that any patent rights would exist or that Gilead would need a license for Truvada for PrEP. *Id.* at 13. "It was only when the government obtained patent rights and asserted them against Gilead that it caused Gilead's damages." *Id.* Gilead therefore argues that its complaint filed in April 2020 is timely. *Id.* at 12. Gilead avers that the government's use of reliance and restitution damages based on the materials provided under the MTAs is misguided because "the purpose of the agreements . . . were [*sic*] not frustrated until the government obtained patents and asserted them against Gilead." *Id.* at 14. Gilead also argues that if the court finds that the complaint is not timely, that the accrual-suspension doctrine applies because the government concealed the patent applications, which breached the contract, until at least 2014 when the NIH, on behalf of the CDC patent portfolio, sent an email to Gilead about licensing and referenced the patent application number. *See id.* at 14-16.

Gilead's claims are not barred by the statute of limitations. The statute of limitations was not triggered until the patent issued in 2015. "Until the patent is issued, there is no property right in it; that is, no such right as the inventor can enforce. Until then there is no power over its use, which is one of the elements of a right of property in anything capable of ownership." *Marsh v. Nichols, Shepherd & Co.*, 128 U.S. 605, 612 (1888)). Therefore, Gilead did not suffer damages until 2015. Before then, it was unknown if the government would receive a patent and therefore have a right to enforce, causing damages. Indeed, the application had been rejected by the patent examiner four separate times before the application was completely amended in 2014. *See supra*, at 13. In addition, the government only provided notice to Gilead in 2014 when NIH sent the licensing email.

2. Substantial compliance.

The substantial-compliance or substantial-performance doctrine "refers to the equitable doctrine that guards against forfeiture in situations where a party's contract performance departs in minor respects from that which has been promised." *Franklin E. Penny Co. v. United States*, 207 Ct. Cl. 842, 856 (1975). It serves to protect plaintiffs, not defendants. *See* 15 Williston on Contracts § 44:52 (4th ed. 2022) ("The purpose of the doctrine is to protect a plaintiff who has performed its promises under the contract so substantially that the defendant has received essentially what it bargained for."). In short, the defendant, the government, cannot invoke this argument against the plaintiff.

3. No implied waiver of MTA claims.

The implied-waiver doctrine requires that the party waiving a claim have knowledge. "The elements of [waiver by implication] are 'failure to terminate within a reasonable time after the default under circumstances indicating forbearance' and 'reliance by the [defaulting party] on the failure to terminate and continued performance by him under the contract, with the [nondefaulting party's] knowledge and implied or express consent.'" *Ho v. United States*, 49 Fed. Cl. 96, 105-06 (2001) (quoting *DeVito v. United States*, 188 Ct. Cl. 979, 991 (1969)). There is no waiver by Gilead. It did not have knowledge to waive MTA claims because the government did not "promptly notify" Gilead of its invention. *See infra*, Section B.

The government's affirmative defenses fail and therefore the court has jurisdiction.

B. Alleged Breaches of the MTAs

1. Government's duties under the MTAs.

The government was obligated to promptly notify Gilead of patent applications under the IP provision of the MTAs. The MTAs required that the government (1): "disclose to [Gilead] all results, data, and other information or materials," (2): "promptly notify [Gilead] of any Inventions," defined as "any inventions, discoveries and ideas that are made, conceived or reduced to practice under [the] [a]greement," and (3): "give serious and reasonable consideration to [Gilead's] request for a non-exclusive or exclusive license on commercially reasonable terms." JX3 at 3; JX5 at 3; JX6 at 3-4.

2. Contract interpretation.

When interpreting a contract, one must first look to the plain language of the contract. *See Telzrow v. United States*, 127 Fed. Cl. 115, 122 (2016) (citing to *Coast Fed. Bank, FSB v. United States*, 323 F.3d 1035, 1038 (Fed. Cir. 2003)). "If the provisions are clear and unambiguous, they must be given their plain and ordinary meaning." *Telzrow*, 127 Fed. Cl. at 122 (quoting *Bell/Heery v. United States*, 739 F.3d 1324, 1331 (Fed. Cir. 2014)). "A contract must also be construed as a whole and in a manner that gives meaning to all of its provisions and makes sense." *Telzrow*, 127 Fed. Cl. at 122-23 (quoting *Bell/Heery*, 739 F.3d at 1331).

Industry custom and usage can also play a role in contract interpretation. A generally accepted industry custom and usage is incorporated by implication. *Flour Mills of Am., Inc. v. United States*, 109 Ct. Cl. 116, 151 (1947). As a leading treatise states:

> Courts will generally accept the definition employed in the relevant industry unless those terms are legislatively or judicially defined . . . . [I]f words in a contract have a special meaning or usage in a particular industry, then members of that industry are presumed to use the words in that special way, whatever the words mean in common usage and regardless of whether there appears to be any ambiguity in the words. A specialized industry or trade term used in a contract may require extrinsic evidence of the commonly understood meaning of the term within a particular industry.

12 Williston on Contracts § 34:5 (4th ed. 2022).

3. Government's breach of the MTAs.

The parties agree that the government largely complied with the first requirement, *i.e.*, that the government disclosed the results of the studies, but they disagree about the government's compliance with the second and third requirements. Gilead argues that the government did not give prompt notification of its patent application, Pl.'s Post-Trial Br. at 31-32, and therefore, Gilead could not have been given serious and reasonable consideration to a license. *Id.* at 32. Gilead argues that the government's various post-application publications did not promptly and effectively notify Gilead. *Id.* at 34-49. The government first points to the prompt notification of the results from the MTA studies. Def.'s Post-Trial Br. at 5, 22-23. Then, it argues that it promptly notified Gilead of the patent application through the 2008 *PLoS Medicine* article's

competing-interest section, in addition to other articles' competing-interest sections, CVs, employment forms, and public or standardized notifications. *Id*. at 22-30. The government also contends that it offered Gilead a license on commercially reasonable terms in 2014. *Id*. at 5, 56.

The government's contentions in this regard are unavailing. It did not promptly notify Gilead of the patent applications, which were "made, conceived or reduced to practice" under the MTAs. The requirement to promptly notify includes "Inventions" "made, conceived or reduced to practice under this Agreement." JX3 at 3; JX5 at 3; JX6 at 3. Inventions include patents because "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101. A "claimed invention" is "the subject matter defined by a claim in a patent or an application for a patent." 35 U.S.C. § 100(j). The provisional patent application was "made, conceived or reduced to practice under" the MTAs because the application was based on the monkey studies that used Gilead's drugs, which were provided under the MTAs. The provisional patent was based on results from studies conducted under the '471 MTA and '649 MTA, Tr. 1403:8-11 (Heneine), *see* Am. Joint Stip. ¶¶ 39, 46, 54, and the '072 MTA, *see* PX447 at 7; Tr. 759:18-24 (Ghosh).[23]

The duty to promptly notify is interpreted in accord with its plain meaning and industry usage. Notify means "to give formal notice to." *Notify*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/notify (last visited Nov.17, 2022). Notify is a verb; it requires an action. Promptly means "without delay**:** very quickly or immediately." *Promptly*, Merriam-Webster.com, https://www.merriam-webster.com/dictionary/promptly (last visited Nov.17,2022). Considering use within industry, Gilead's technology transfer expert, Dr. Blakeslee, stated that the duty to notify would include "what th[e] invention is . . . the title to the invention so you knew the subject matter area of the invention . . . . [a]nd . . . what material transfer agreement was this invention made under." *See* Tr. 997:13 to 998:24 (Blakeslee). Dr. Blakeslee also stated that promptly means "within a very short time after you have made the determination that you've got the duty and obligation, in this case by the time the provisional was filed." Tr. 1037:14-17 (Blakeslee). A government expert, Dr. Sheridan, countered that "there is no industry standard definition of 'prompt notification,'" Tr. 1831:10-11 (Sheridan), but he was unable to "recall a single occasion . . . where [the obligor] waited more than a year to provide notification of an invention after becoming aware of an obligation to do so[.]" Tr. 1912:18-22 (Sheridan).

In addition to considering the plain meaning and the industry usage, the duty to promptly notify should be interpreted in a way that gives meaning to all parts of the MTAs. To be able to exercise its rights under the MTAs, Gilead would need to know about the government's patent application. Under the MTAs, the government must give Gilead "serious and reasonable consideration to [a] request for a . . . license." JX3 at 3; JX5 at 3; JX6 at 3. Gilead's ability to exercise this right is forestalled if it does not know a patent application exists, especially in a timely manner. Being promptly notified would be important for Gilead to exercise its rights under the contract. *See* Tr. 997:13 to 998:24 (Blakeslee).

The government did not notify Gilead until October 23, 2014, when the NIH sent an email to Gilead on behalf of the CDC inquiring about Gilead's interest in licensing Truvada for

[23] The study under the '072 MTA was the TDF-only experiment referenced in the issued patent. *See* DX418 at fig. 2.

PrEP.[24] Although similar emails were sent to other companies, the email constituted effective notification to Gilead because it included details about the subject matter of the technology invented, a statement that the CDC was pursuing patent protection, and a link to the *Federal Register*, which provided additional details and listed the provisional and non-provisional patent application numbers. *See* DX43; DX572. Although this email did not reference the MTAs under which the technology was developed, the description of the technology was sufficiently tied to the studies under the MTAs. Among other things, it stated that the prophylaxis was achieved by combining FTC and TDF (Truvada) and that it was tested in macaque monkeys. *See* DX43 at 7. Even so, the government's notification was not prompt because it was sent eight years after the government filed the provisional patent application. In addition, the government's 2016 email to Gilead notified the company, but it also was not prompt because it was ten years after the provisional patent application was filed and after the patent was issued. *See* DX577 at 2514706.

The government errs in urging that its sharing of the results of the studies under the MTAs satisfied its duty to promptly notify Gilead. *See* Def.'s Post-Trial Br. at 5. The government relies on articles publishing the results of the studies and presentations given at the 2007 HIV Prevention Trial Network, *see* PX124 at 4; Tr. 1418:25 to 1422:4 (Heneine), and the 2008 CROI Conference, *see* Tr. 1429:9-18 (Heneine), for example. This argument conflates the first and second requirements in the MTAs. The government has both a duty to share the results of the studies under the MTAs *and* a duty to promptly notify Gilead of any inventions "made, conceived or reduced to practice" under the MTAs. JX3 at 3; JX5 at 3; JX6 at 3. Simply providing the results of the studies, including the presentations that discussed the results, did not satisfy the government's duty to promptly notify Gilead of any inventions.

The government also incorrectly concludes that the 2008 *PLoS Medicine* article's competing-interest section promptly notified Gilead. That cryptic section generically referred to "HIV prophylaxis" and did not include the patent application number or title or the MTAs. Tr.

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[24] The email from the NIH, on behalf of the CDC, stated:

> In light of your recent and ongoing interest in and success with Truvada, your company appears to be an ideal partner for a technology developed by Dr. Walid Heneine at the Centers for Disease Control and Prevention (CDC).
>
> Dr. Heneine's group has shown that daily pre-exposure prophylaxis (PrEP) with emtricitabine in combination with tenofovir disoproxil fumarate (Truvada) significantly increases the level of protection against HIV transmission. This finding was discovered following repeated virus challenges with macaque monkeys. The CDC is pursuing U.S. and foreign patent protection for this technology.
>
> An abstract with more information can be found in the Federal Register. Also, Dr. Heneine has coauthored publications in *PLoS Medicine* and *Science Translational Medicine*, describing the above discovery. Please contact me if I can be of further assistance.

DX43 (emphasis added).

1431:23 to 1433:8 (Heneine).[25] Even further, the references in a competing-interest section do not necessarily "directly relate[] to the content of the manuscript," *see* Tr. 366:18 to 367:5, Tr. 385:2-7 (Rooney), and prophylaxis can relate to "multiple different things," *see* Tr. 433:4-7, Tr. 384:11-16 (Rooney). In addition, the cover email that Dr. Heneine sent to Dr. Rooney and Dr. Lee, of Gilead, attaching the article, did not contain information about the patent applications.[26] Dr. Heneine stated that "[he] was just sharing the publication, the final official publication." Tr. 1431:5-18. (Heneine). Moreover, the alleged notification was not prompt because the article was sent to Gilead approximately two years after the filing of the provisional patent application. The government thought it had an invention triggering its duty to promptly notify at least at the filing of the provisional patent application. Tr: 1994:16-19, Tr. 1997:17-23 (Heneine); Tr. 769:2-12 (Ghosh); Tr: 1171:7 to 1173:3 (Shope); Tr. 1945:20 to 1946:25 (Sheridan), Tr. 2345:9 to 2346:9 (Blakeslee). Eleven other articles were cited, all published after the *PLoS Medicine* article, but the competing-interest sections also did not give functional notice for similar reasons. Only three of these articles, one published in 2014 and two in 2016, listed a patent application or patent number in the competing-interest section. DX1262; DX1267; DX1268.[27] None of these eleven articles satisfied the notification requirement, and they were not prompt.

Employment forms and CVs similarly did not effectively notify Gilead. First, Dr. Janssen listed the international patent application number, rather than the U.S. patent application number, on his Gilead employment form in 2008. DX128 at Ex. A; DX548 at 65; Tr. 1242:24 to 1243:8 (Janssen); *see* DX552. This could not notify Gilead of the U.S. patent application. Second, Dr. Garcia-Lerma removed references to the patent application from the CV he submitted to Gilead as part of a job application in 2012. Tr. 650:6 to 651:24; 654:5 to 655: 24 (Garcia-Lerma). Although Dr. Heneine sent his CV, which included the provisional patent application number, to Gilead when exploring jobs there in 2008 and 2010, they were not reviewed and were submitted for the purpose of exploring jobs. DX854 at 4; Tr. 1284:6 to 1285:21 (Lee). Regardless, none of these alleged notifications were prompt because they were at least two years after the filing of the provisional patent application.

In addition, generic notices in CDC publications also did not promptly notify Gilead. First, the CDC brochures, which listed technologies for license covered by HHS Patents, were not sent to Gilead, *see* Tr. 767:25 to 768:3 (Ghosh), and therefore cannot satisfy the government's duty to affirmatively notify Gilead. Second, the *Federal Register's* 2014 list of pending patent applications was published by the CDC "to advertise [its] technologies broadly." Tr. 1700:4-9 (Kirby). The publication, standing alone, did not satisfy the government's duty

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[25] The competing-interest section in the 2008 *PLoS Medicine* article stated, "Competing Interests: Authors JGGL, RAO, RJ, TMF, and WH are named in a US Government patent application related to methods for HIV prophylaxis." DX425 at 1.

[26] The email stated "Jim, This is a heads up for the publication of our paper next week in *PLoS Medicine*. Bill- This paper describes the monkey model we use and PrEP efficacy data, along what we have discussed on Thursday. I will see you both in Boston. Regards Walid." DX443.

[27] The article published in 2014 listed a patent application number and title. *See* DX1262. One article published in 2016 listed a patent number and stated it was granted on June 2, 2015, DX1267, and the other article published in 2016 listed a patent application number, DX1268.

because it was not directed at Gilead, and it was not prompt because the notice was published eight years after the filing of the provisional patent application. Third, even though a 2008 *Derwent Patent Index* described the non-provisional U.S. and the international patent application, this was an internal email from a service to which Gilead subscribed, and therefore cannot satisfy the government's affirmative duty to notify Gilead. DX637 at 1209478; *see* Tr. 1287:21 to 1288:23 (Lee). Regardless, it was not prompt. As discussed, the 2014 NIH licensing email and the 2016 email effectively notified Gilead, but the notice was not prompt because it was sent eight years and ten years, respectively, after the provisional patent application was filed.

In sum, the government did not promptly notify Gilead of its inventions under the MTAs and therefore breached the MTAs.

C. Alleged Breaches of the CTAs

1. Government's obligations under CTAs.

Under the Extended Safety Study CTA and the Botswana CTA, the government was obligated to "put the results of the Trial, patentable or otherwise, in the public domain for all to use without obligation or compensation to CDC." JX1 at 3; JX2 at 3. The CTAs also stated, "For clarity, CDC agrees not to seek patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial." JX1 at 3; JX2 at 3. The Trial is defined as the study (the Extended Safety Study and the Botswana study) under the CTAs. *See* JX1 at 2; JX2 at 2. For the Extended Safety Study, the Study Drug is defined as TDF. JX1 at 2. For the Botswana study, the Study Drug was initially defined as TDF, JX2 at 2, but then amended to a combination of TDF and FTC (Truvada) in September 2006, *see* JX8 at 1.

2. Contract interpretation.

Contracts should be interpreted according to their terms' plain and ordinary meaning if the provisions are unambiguous. *Telzrow*, 127 Fed. Cl. 122 (quoting *Bell/Heery*, 739 F.3d at 1331). "When interpreting contracts, courts are instructed to consider the contract 'as a whole' and adopt an interpretation that 'harmonize[s] and give[s] meaning to all of [the contract's] provisions.'" *Boston Edison Co. v. United States*, 152 Fed. Cl. 358, 363 (2021) (quoting *Julius Goldman's Egg City v. United States*, 697 F.2d 1051, 1057-58 (Fed. Cir. 1983)).

3. Evidentiary issues bar a determination whether the government breached the CTAs.

Gilead argues that the CTAs contain two separate requirements and that the government breached both. Pl.'s Post-Trial Br. at 49-50. The first requirement obligates the government to "put the results of its clinical trials in the public domain" for anyone to use without compensating the CDC. Gilead states that results include clinical trial data, analysis, and conclusions. *Id.* at 50. The results of the Extended Safety Study "[are] that a daily TDF-based PrEP regimen 'was well tolerated, with reasonable adherence' and '[n]o significant renal concerns were identified' in men who have sex with men.'" *Id.* at 51 (quoting PX228 at 1). The results of the Botswana study "[are] that daily Truvada® [TDF and FTC] 'prophylaxis prevented HIV infection in sexually active heterosexual adults." *Id.* at 51 (quoting DX1090 at 14-15). Gilead argues that patenting the invention, which includes "the safe and effective use of TDF with FTC for humans

– including both [men who have sex with men] and heterosexual men and women . . . . prior to exposure to HIV" takes the results out of the public domain and contravenes the terms of the CTAs. *Id*. at 50-52.

Gilead emphasizes that the second requirement prohibits the government from "seek[ing] patent protection in connection with any inventions that derive from the use of the Study Drug in the Trial." JX1 at 3. Gilead argues that the second requirement is a separate requirement because the first covers both patentable and unpatentable content, while the second only covers patentable content. Pl.'s Post-Trial Reply Br. at 8. Gilead states that "derived from" should be given its ordinary meaning, including "came out of," "arose from," Tr. 88:5-7 (Alton), "results from," "emanates from," or "comes from," the trials, Tr: 1820:5-12 (Sheridan) (agreeing with terms Dr. Blakeslee used). Pl.'s Post-Trial Br. at 53. Gilead argues that the government breached the second requirement because the patents derive from the use of TDF in the Extended Safety Study. Gilead avers that if TDF was shown not to be safe then it would affect "other ongoing PrEP studies evaluating the efficacy of TDF-based PrEP regimens," as well as the use of TDF and FTC in the Botswana study, because that study included women and the patent covered all people. *See* Pl.'s Post-Trial Br. at 53-54.

The government argues that the CTAs only include one requirement, contending that the two sentences mean "the Government would not seek patent protection from any 'inventions' that derive from *the results* of these trials." Def.'s Post-Trial Br. at 44 (emphasis added). The government focuses on the term "results," arguing that the inventions in the second sentence are limited to the results of the trials. *See id*. at 44-45 ("[Gilead] incorrectly removes any meaningful limitation on the trial 'results' to which the Government agreed not to seek patent protection. This reading is flawed and incorrect because it untethers the subject Trials' 'results' from the inventions that are mandated to be put in the 'public domain.'") (citation omitted). Relatedly, the government also reasons that because the second sentence starts with "[f]or clarity," which clarifies what came before, Tr. 1938:19-23 (Sheridan), there are not two separate requirements, *see id*. at 46. While the government agrees with Gilead that "derive from" should be given its plain meaning, it argues that the phrase "derive from the use of the Study Drug in the Trial," JX1 at 3, JX2 at 3, shows that the inventions in the patents did not "derive from" the two CTA studies because their results were not fully collected and published until after the provisional patent application in 2006 and the non-provisional patent application was first filed in 2007. *See* Def.'s Post-Trial Br. at 46-47. The government argues that Gilead's position eliminates any time constraint from "derived from the use of the Study Drug in the Trial." *Id*. It continues to urge that the inventions in the HHS Patents did not derive from the Extended Safety Study because the study only evaluated the safety of TDF and the first patent issued covers a combination of TDF and FTC. *See id*. It further notes that it was very unlikely that it would have been halted for safety concerns given the previous use of TDF for HIV treatment. *See id*. at 48. The government also claims that it did not cite to or rely on the Extended Safety Study or the Botswana study during the patent prosecution. *Id*. at 49. It therefore argues that it did not breach the CTAs. Notably, however, that omission may be a matter of avoidance on the part of the patent applicants. Prior relevant administrative proceedings had prominently cited and relied on those studies.[28]

[28] In approving use of Truvada for PrEP in 2012, *see supra*, at 10, the FDA relied on the clinical trials conducted under the CTAs, among other studies. *See generally* JX38. The 2014 patent application only cited to and included one article, the Massud article, that mentioned FDA

The CTAs contain two separate but related obligations for the government. The first obligation is a requirement to put the results in the public domain. The second obligation is a prohibition on seeking patent protection on inventions derived from using TDF in the Extended Safety Study or TDF and FTC (Truvada) in the Botswana study. The second obligation clarifies, or builds upon, the first, and therefore the CTAs contain two separate obligations. The first requirement covers both patentable and unpatentable results, while the second prohibition covers only patentable inventions, since it puts any such inventions in the public domain and prohibits the government from seeking patent protection. This prohibition would not be necessary for unpatentable content because, by definition, such content cannot be patented.

Overall, at this stage, there is insufficient evidence to determine if the government complied with the two obligations in the CTAs, to "put the results in the public domain" for anyone to use without compensating CDC and "not to seek patent protection in connection with any inventions that derive from use of the study drug in this trial." JX1 at 3; JX2 at 3. First, the Extended Safety Study concluded that oral TDF was safe for long-term use in uninfected men. PX228 at 1; Tr. 875:11-18 (Celum); Tr. 692:15 to 693:19 (Paxton). The Botswana Study concluded that "[d]aily [oral] TDF-FTC prophylaxis prevented HIV infection in sexually active heterosexual adults." DX1090 at 14. These are the results of the two trials. The government presented the results of the Extended Safety Study at the International AIDS Conference in 2010, PX180 at 222862, and published the results of the Botswana study in the *New England Journal of Medicine* in 2012, DX1090 at 14. But it is not apparent whether the patent examiner considered the results of the Extended Safety Study and the Botswana study.[29] If he did, this would take the results out of the public domain and require "obligation or compensation to [the] CDC" to use the results, violating the first obligation. JX1 at 3; JX2 at 3. Although the results of the two trials relate to the content of the patented invention, the record is incomplete regarding whether the patent examiner took them into consideration and patented them when issuing the patent in 2015, as discussed below.

Second, but relatedly, there is insufficient evidence to determine if the government complied with the second obligation. The patents may or may not have been "derived from" use of TDF in the Extended Safety Study or TDF and FTC in the Botswana study. The government

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approval of Truvada for PrEP in one paragraph. JX23 at 769, 670. The article discussed a study of a different drug that proved ineffective for HIV PrEP. *Id.* at 670. The patent examiner may have had access to the FDA's findings and conclusions in evaluating the patent application as recast in 2014. Whether the patent examiner was aware of the FDA's findings remains to be determined.

[29] Only the Massud article, which is cited to and included in the 2014 patent application, in turn cites the Botswana trial when mentioning FDA approval of Truvada for PrEP. The citation supports the sentence "[t]here human clinical trials with daily FTC-TDF among men who have sex with men and heterosexually active men and women have provided proof of concept that daily PrEP can prevent sexual HIV transmission." JX23 at 670. The Massud article was provided to the patent examiner in 2014 to show "[e]vidence of [u]nexpected [s]uperior [r]esults" because the study in this article "failed to protect against rectal infection [of HIV] in a macaque model." *Id.* at 576-77. The Botswana article, standing alone, is not cited to, or included in the patent application itself.

is incorrect that the patented invention could not be derived from the CTA trials because their results were not finalized until after the provisional patent application and non-provisional patent application were first filed in 2006 and 2007, respectively. The 2014 patent application, which completely amended the applications, was filed after the final data in the two CTA trials had been collected and results had been published. PX228; PX180; DX1090.

The issued patent application did not cite either the Extended Safety Study or the Botswana study. *See generally* JX23. The only human trial cited in the issued patent application was the iPrEx trial (the Grant study), conducted by the NIH, which studied whether a combination of TDF and FTC delivered orally was safe and effective in men who have sex with men and transgender women. DX1292 at 1; JX23 at 569-78, 769; Tr. 812:2 to 813:8 (Siegel). The Botswana study was not cited in the issued patent application; however, it was cited as a footnote in an article cited in the application. JX23 at 769; *see supra*, at 23 n. 29.

These unresolved matters presumably will be put before the district court in the patent trial, and that court then would have a better record for determination of the pertinent facts.

D. Damages

Damages serve to make the nonbreaching party whole. *Glendale Fed. Bank, FSB* v. U.S., 239 F.3d 1374, 1380 (Fed. Cir. 2001). Reliance damages allow the non-breaching party to "'recover expenses of preparation of part performance, as well as other foreseeable expenses incurred in reliance upon the contract.'" *Hansen Bancorp, Inc., v. United States*, 367 F.3d 1297, 1309 (Fed. Cir. 2004) (quoting John D. Calamari & Joseph M. Perillo, *The Law of Contracts* § 14.9 (4th ed. 1998). Restitution damages seek to return any benefit the breaching party gained to the non-breaching party. *See* Restatement (Second) of Contracts § 373. Expectation damages give the non-breaching party "the benefits [it] . . . expected to receive had the breach not occurred." *Anchor Sav. Bank, FSB v. United States*, 597 F.3d 1356, 1361 (Fed. Cir. 2010). The benefits are typically equated with lost profits but can be equated with other damages as well. Glendale, 239 F.3d at 1380. To be awarded expectation damages, the non-breaching party "must establish by a preponderance of the evidence that (1) [damages] were reasonably foreseeable or actually foreseen by the breaching party at the time of contracting; (2) [damages] [were] caused by the breach; and (3) the amount of the [damages] has been established with reasonable certainty. *Anchor*, 597 F.3d at 1361 (citing *Cal. Fed. Bank v. United States*, 395 F.3d 1263, 1267 (Fed. Cir. 2005); *Energy Cap. Corp. v. United States*, 302 F.3d 1314, 1324-25 (Fed. Cir. 2002)). Foreseeability for purposes of determining contract damages requires "merely that the injury actually suffered must be one of a kind that the defendant had reason to foresee and of an amount that is not beyond the bounds of reasonable prediction." 11 Joseph M. Perillo, Corbin on Contracts § 56.7 (rev. ed. 2022).

Gilead argues that it suffered reliance, restitution, and expectation damages. It argues that its restitution and reliance damages are "based on the cost or the value of materials that were transferred under the MTAs and the CTAs." Pl.'s Post-Trial Br. at 56-57 (quoting Tr. 2056:13-15 (Schenk)). Gilead argues that it suffered expectation damages for the breaches under the MTAs because the government's failure to promptly notify "deprived Gilead of the opportunity to contemporaneously negotiate a relatively low-cost or royalty-free license when the government first decided it had an Invention." *Id.* at 57. Gilead also argues that it suffered

expectation damages for the breaches under the CTAs, including the legal fees that it has paid in the patent infringement suit in Delaware. *Id*. at 56-57.

The government argues that although Gilead suffered reliance and restitution damages, they are unrecoverable because they are time barred. The government also argues that Gilead did not suffer expectation damages. The government agrees with Gilead that reliance and restitution damages are tied to the cost or value of the materials provided under the agreements. Def.'s Post-Trial Br. at 60-61. The government argues, though, that these damages are unrecoverable because they were suffered in 2006, when the government alleges the breach occurred, and therefore are time barred under the six-year statute of limitations. *Id*. at 59, 62. The government also argues that Gilead did not suffer expectation damages from the alleged breaches of the MTAs or CTAs. *Id*. at 62-73. The government claims that Gilead has not proven that it suffered increased licensing fees and loss of evidence or that it suffered damages from the Delaware litigation. *Id*.

For this bifurcated trial, Gilead has sufficiently proven that it suffered reliance, restitution, and expectation damages. Gilead suffered reliance and restitution damages based on the cost of the materials provided. Despite the government's argument that Gilead's reliance and restitution damages were suffered in 2006, Gilead did not know of the application was filed until 2014, *see supra*, at 17-21. Moreover, Gilead did not suffer damages until the patent was issued in 2015.[30] Gilead's reliance and restitution damages are not time-barred. In addition, Gilead has shown that it suffered expectation damages under the MTAs because the government's failure to promptly notify inhibited it from negotiating a license when the government first arguably had an invention, while Gilead retained its patent in Truvada.

At the liability stage in this bifurcated case, Gilead has sufficiently established that it suffered reliance, restitution, and expectation damages.

CONCLUSION

For the reasons stated, the court finds that the government breached the MTAs by failing to provide prompt notification of "any Inventions" derived from the work under the agreements. Thus, the court finds defendant liable for breach of the MTAs. As noted, the court reserves decision on whether the government breached the CTAs.

It is so **ORDERED**.

s/ Charles F. Lettow
Charles F. Lettow
Senior Judge

[30] Again, unbeknownst to Gilead, the patent application was denied at least four times before it was issued in 2015. Tr. 804:8-11 (Siegel).